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| | Application No. | Applicant(s) |
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| Notice of Allowability | 10/808,347 | KRANTZ ET AL. |
| | Examiner | Art Unit |
| | Jaworski Francis J. | 3768 |
| The MAILING DATE of this communication appe All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RI of the Office or upon petition by the applicant. See 37 CFR 1.313 | (OR REMAINS) CLOSED in this a or other appropriate communication IGHTS. This application is subject | application. If not included on will be mailed in due course. THIS |
| 1. \boxtimes This communication is responsive to $\underbrace{Int.12/12,amdt12/18}$. | | |
| 2. ☑ The allowed claim(s) is/are <u>1-26</u> . | | |
| Acknowledgment is made of a claim for foreign priority ur a) All b) Some* c) None of the: 1. Certified copies of the priority documents have 2. Certified copies of the priority documents have 3. Copies of the certified copies of the priority documents have International Bureau (PCT Rule 17.2(a)). * Certified copies not received: | been received. been received in Application No. | |
| Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONM THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. | of this communication to file a repl IENT of this application. | y complying with the requirements |
| A SUBSTITUTE OATH OR DECLARATION must be subm INFORMAL PATENT APPLICATION (PTO-152) which give | itted. Note the attached EXAMINE es reason(s) why the oath or decla | R'S AMENDMENT or NOTICE OF ration is deficient. |
| 5. CORRECTED DRAWINGS (as "replacement sheets") mus | st be submitted. | |
| (a) 🔲 including changes required by the Notice of Draftspers | | D-948) attached |
| 1) 🗌 hereto or 2) 🔲 to Paper No./Mail Date | | |
| (b) ☐ including changes required by the attached Examiner's Paper No./Mail Date | s Amendment / Comment or in the | Office action of |
| Identifying indicia such as the application number (see 37 CFR 1 each sheet. Replacement sheet(s) should be labeled as such in t | .84(c)) should be written on the draw he header according to 37 CFR 1.12 | vings in the front (not the back) of 1(d). |
| DEPOSIT OF and/or INFORMATION about the depo- attached Examiner's comment regarding REQUIREMENT | | |
| | | |
| Attechment(s) 1. [일 Notice of References Cited (PTO-892) | 5. Notice of Informal | Patent Application |
| 2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) | | * * |
| | 6. X Interview Summar Paper No./Mail D 7. | ate 12/12/66 dment/Comment |
| 3. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 2-4-05 | | |
| Examiner's Comment Regarding Requirement for Deposit of Biological Material | | nent of Reasons for Allowance |
| | | Francis J. Laworski Primary Examiner |

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REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

Geiser et al (US5797396) uses elliptical filters to model an outline of the heart including the fetal heart for purposes of producing conventional volumetric indices from the outlines.

Weng Jr et al (US5588435) and Chalana et al (US5605155) are directed to the use of approximating functions on an ultrasound image in order to generate fetal measurement parameters.

Fan et al (US7022073) is directed to the use of gradient operations to define organ outlines.

Weiss et al (US5898797) related to the prior-cited Weiss et al patent does not teach use of functional coefficients as opposed to distribution of measured values as a biomarker, as argued by applicants in the April 20, 2006 amendment.

Spratt (5838592) produces fetal head circumference values as the length of an image- fitted curve.

Taylor (US6491632) is directed to photogrammetric monitoring using ultrasoundderived images.

Dewuele(6792071) is directed to e.g. bone measurements made on digitized radiographic images with reference to stored anatomic bone template depictions.

O'Donnell et al(6873718) is directed to the use of statistical shape modelling to determine cardiac-specific contours.

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Johnson (US2003/0160786) pertains to automatic heart shape outline tracing in contrast to manual contour identification in fetal scans.

Littlefield et al (US7127101) is cited as of general interest in using MRI to correct infant cranial defects using cranial remodeling models.

Rottem (US6032678) is directed to comparative fetal image analyses to determine abnormalities.

Parker et al (US2004/0147830) is directed to image segmentation e.g. of the fetal head to produce a biomarker for tracking over time based upon measured values.

Krantz et al (US2005/074783) was considered for obvious-type double patenting issues however the claims are directed therein to the use of a measured value ratio as a fetal biomarker including a production of a likelihood ratio therefrom as opposed to the use of shape function coefficients.

Krantz et al (US2005/245825) is directed to claiming of statistical analysis of likelihoods based upon landmark points derived from a fetal image as opposed to a determination of coefficients of a shape function for the points.

The claims as amended were considered to define over fetal cell shape analysis and statistical coefficients associated with cell population results.

None of the prior art alone or in combination teaches or suggests a computer – implemented method or a processor having resident software therein for receiving coordinates identifying an anatomic shape of a human fetus together with determining mathematical function coefficients for the identified shape and thereafter using the

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coefficients themselves not the measured shape or measured shape statistics per se as

biomarker(s) of fetal abnormality...

Any comments considered necessary by applicant must be submitted no later

than the payment of the issue fee and, to avoid processing delays, should preferably

accompany the issue fee. Such submissions should be clearly labeled "Comments on

Statement of Reasons for Allowance."

Any inquiry concerning this communication should be directed to Jaworski

Francis J. at telephone number 571-272-4738.

FJJ:fjj

12-28-06

Primary Éxaminer

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